



PEC UPDATE

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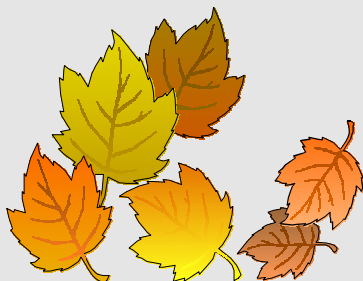
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Drug Safety Information from the FDA

The Food and Drug Administration (FDA) now has drug safety-related information available through the MEDWATCH Web site. One feature in the 'Safety Information' section is the "Dear Health Professional" letters and other safety notifications. Summaries and full text versions of individual notifications from 1996 through the present are available.

Another feature in the 'Safety Information' section is the approved drug labeling changes related to drug safety. Summaries for safety-related labeling changes for already approved drugs are prepared in cooperation with FDA's Center for Drug Evaluation and Research. Summaries for changes made from July 1996 through June 1997 are available, but only include safety-related sections that have been modified, and thus do not contain full prescribing information.

In addition, the 'Safety Information' section contains the Medical Device Reporting data files and the Adverse Drug Reaction (ADR) Reporting data files. These files contain all medical device reports submitted to the FDA through August 1996, and all the ADR reports submitted through the Spontaneous Reporting System and processed by the FDA through mid-January 1997. These files are available for downloading.

Finally, the FDA Enforcement Report can be found in the 'Safety Information' section of the web page. This report is published weekly by the FDA, US Public Health Service, and the Department of Health and Human Services and contains information on actions taken in connection with agency regulatory activities. Drug recalls and field notices can be found in this report.

To access the FDA's MEDWATCH home page for further information, point your Internet browser to: < <http://www.fda.gov/medwatch> >. The MEDWATCH page and other features can also be

accessed through the FDA's Center for Drug Evaluation and Research, Drug Information Section at: < <http://www.fda.gov/cder/drug.htm> >.

Request for Information— Hyperlipidemia Review

The PEC is re-evaluating data for a pharmacoeconomic analysis of the treatment of hyperlipidemia. Hyperlipidemia was originally reviewed in PEC Update 96-01 (16 October 1995); however, since the original review, new data have been reported and new drugs have come to the market.

To help us develop the most appropriate analysis for this disease state, we would like to hear how practitioners in the field are managing patients with hyperlipidemia. The PEC is also interested in any treatment protocols, critical pathways, results of drug usage evaluations, data from outcomes studies, innovative patient education programs or monitoring tools, or other information related to the diagnosis and treatment of hyperlipidemia that you are willing to share. If you have any questions regarding this disease state review, please contact LTC(P) Dan Remund at (210) 295-9642 or DSN 421-9642.

In the Literature..... Treatment Guidelines

United States Public Health Service (USPHS) and Infectious Diseases Society of America
Centers for Disease Control and Prevention. 1997 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. *MMWR* 1997;46 (No. RR-12):1-46.

See accompanying Editorial:

Kaplan JE, Masur H, Jaffe HW, Holmes KK. Preventing opportunistic infections in persons infected with HIV: 1997 guidelines. *JAMA* 1997;278:337-8.

The guidelines are available to download from the Center for Disease Control and Prevention (CDC) web page at: < http://www.cdc.gov/epo/mmwr/mmwr_rr.html >. Additionally, reprints of the guidelines are available at: CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20849-6003; or by telephone at 1-800-458-5231.

Studies Conducted at MTFs

The following published studies were conducted in military medical treatment facilities (MTFs) and may be useful to other MTF practitioners. If you have a study that was conducted in your MTF, please let us know.

Marple RL, Kroenke K, Lucey CR, Wilder J, Lucas CA. Concerns and expectations in patients presenting with physical complaints: frequency, physician perceptions and actions, and 2-week outcome. *Arch Intern Med* 1997;157:1482-88.

- This study prospectively evaluated adult outpatients presenting with physical complaints to determine the frequency of symptom-related patient concerns and expectations, physician perceptions and actions, and the relationship of these factors to symptom outcome and satisfaction with care. Patients completed pre-visit and 2-week follow-up questionnaires, and physicians completed a post-visit questionnaire. Satisfaction with care in patients with physical complaints might improve with increased recognition of symptom-related concerns and expectations.

Randall DC, Jones DL. Eliminating unnecessary lactate dehydrogenase testing: a utilization review study and national survey. *Arch Intern Med* 1997;157:1441-4.

- This study describes the results of a utilization review evaluating the impact of removing lactate dehydrogenase (LDH) and LDH isoenzyme tests from the diagnostic panel to rule out myocardial infarction (ROMI). Results confirm that routine LDH isoenzyme testing provides little benefit, and removal of LDH testing from routine ROMI protocol may provide substantial savings.

Cumulative Index of PEC Disease State/Drug Category Reviews and Guidelines

This index provides a cumulative listing of the disease state or drug category reviews completed by the PEC. Copies of these documents can be obtained directly from the PEC or downloaded from the PEC Home Page on the World Wide Web at: <<http://www.ha.osd.mil/hppec2.html#Start> >

- Treatment of Benign Prostatic Hyperplasia, 97-08, 16 May 1997
- Pharmacoeconomic Analysis of Obesity Treatment, 97-05, 14 February 1997
- Treatment of Vulvovaginal Candidiasis, 97-01, 15 October 1996 (see 97-07, 14 April 1997, Tri-Service Formulary Selection for Vulvovaginal Candidiasis, for updated information)
- Management of Asthma, 96-11, 16 August 1996
- Pharmacoeconomic Analysis of Typhoid Vaccines, 96-04, 19 January 1996
- Management of Hyperlipidemia, 96-01, 16 October 1995

- NSAIDs and Related Agents for Chronic Arthritic Conditions, 95-08, 15 May 1995
- Acute Respiratory Tract Infections, 95-03, 15 December 1994 (see 95-04, 17 January 1995, for correction)
- Major Depression, 95-02, 10 November 1994 (see 95-06, 17 March 1995, Antidepressant Update, for addendum)
- Acid-Peptic Diseases, 94-09, 25 July 1994
- Hypertension, 94-08, 11 July 1994

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